

U.S. Application No.: 10/689,221
AMENDMENT A

Attorney Docket: 3975.025

REMARKS

The foregoing amendments and these remarks are in response to the Office Action dated February 10, 2006. This amendment is filed with a request for extension of time and authorization to charge Deposit Account No. 50-0951 for the appropriate fees.

At the time of the Office Action, claims 1-21 were pending. Claims 1-13 are rejected, claims 14-21 are withdrawn. Claim 1 is amended to recite process parameters recited in paragraph [00034] of the specification.

Reconsideration is requested in view of the above amendments.

Restriction Requirement

The Examiner maintains the restriction requirement between Group I (Claims 1-13, drawn to a powder mixture for resorbable calcium phosphate biocements, classified in class 556, subclass 308), Group II (Claims 14-20, drawn to a method for manufacturing resorbable calcium phosphate biocements, classified in class 423, subclass 308) and Group III (Claim 21, drawn to a biodegradable implant, classified in class 424, subclass 423), and in view of Applicants election of Group I (with traverse) withdraws claims 14-21.

Applicants respectfully again respectfully request reconsideration of the restriction requirement, particularly in view of the claims as amended.

The Examiner fails with the argument it would be possible to prepare all ingredients separately and mix all together. The Examiner ignores the presence of the amorphous phase (c) which phase also contributes to the parameter "resorbable...biocement". Only the claimed method leads to the biocement with all mentioned parts: the relation of Q₀ and Q₁ groups of orthophosphates and diphosphates, respectively, the Ca₂- and Ca₁₀-phosphates, the mentioned diphosphates and the amorphous phase.

The statement of the Examiner that the calcium phosphate biocement can be made by mixing hydroxyapatite (HA) with CaHPO₄, wetting and milling does not apply to the present process.

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HA is not mentioned under the crystal phases of part b) of Claim 1, neither within the main crystal phases $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$, $\text{Ca}_{10}\text{Na}(\text{PO}_4)_7$, $\text{Ca}_{10}\text{K}(\text{PO}_4)_7$, nor within the secondary crystal phases, because the object of the invention is a powder mixture for resorbable calcium phosphate biocement. As is well known, HA is insoluble in water, only soluble in acids. Accordingly, 97% of the dental enamel is made from HA (see page from the enclosed Wikipedia Encyclopedia). It would be contrary to the object of the invention to include more than subordinate amounts HA in the biocement theoretically.

Further a most important part of diphosphates such as $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, $\text{Ca}_2\text{P}_2\text{O}_7$ is a part of the powder mixture and of the biocement. It seems impossible to use a powder mixture for a biocement of the invention with diphosphates according to the process mentioned by the Examiner.

On the other hand, the inventive process can only be used to produce the product of the invention and no other products.

The invention of Groups II and III are also not distinct from the same reasons as above. The process described by the Examiner is different from the inventive process because in the invention

- at first there is a melting process of the mixtures of raw materials,
- then the melted product is milled to the described different grain fractions,
- after that, the different grain fractions are mixed with water and hardened to an implant.

This process can only be used to make this specific material. On the other side, this product can only be made by this specific process.

Claims Rejections – 35 USC § 112, first paragraph

Claims 1-13 are rejected under 35 U.S.C. §112, first paragraph.

On pages 3-7 of the Office Action the Examiner takes the position that the invention is enabled only to the extent described in paragraph [00034] of the specification.

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While Applicants respectfully disagree, in order to expedite issuance of a first patent Applicants amend claim 1 to incorporate the limitations from paragraph [0034] of the specification.

By that measure the number of powders of which enablement is to be determined is reduced to those more precisely defined in the specification, and the chemist of ordinary skill in the art has no undue burden in experimentation. Reading claim 1 the chemist of ordinary skill in the art knows that orthophosphates such as Ca_3CO_4 and diphosphates such as $\text{Ca}_2\text{P}_2\text{O}_7$ are contained which can be measured by ^{31}P -NMR. Further crystal phases of $\text{Ca}_2\text{K/Na}(\text{PO}_4)_3$ and $\text{Ca}_{10}\text{K/Na}(\text{PO}_4)_7$ are contained which can be measured by X-ray, and an X-ray amorphous phase is present. From that knowledge he is able to control the product by the melting process with the mentioned starting materials and different thermal steps at different temperatures and also the melting temperature in the range of 1550-1650°C and holding times of the melting temperature.

It is usual knowledge of the skilled in the art how the features of a melting product can be influenced. But it is completely new that diphosphates together with the special crystal phase and an X-ray amorphous phase can build a resorbable calcium phosphate biocement with the special fraction mixture.

Accordingly, withdrawal of the rejection is respectfully requested.

Claims Rejections – 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. 19744809 in view of U.S. Patent No. 4,239,113 to Gross et al. and U.S. Patent No. 3,922,155 to Broemer et al. and U.S. Patent No. 6,002,065 to Constantz et al.

The position of the Examiner can be found on pages 7-11 of the Office Action.

Applicants respectfully traverse in view of the claims, as amended.

Applicants are well acquainted with DE 197 44 809, as it concerns the invention of the same inventor Berger. The person of ordinary skill could not take from Berger the teaching for which the Examiner relies on the reference because Berger mentions only that any glassy-crystal

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ceramic material having the same composition of raw materials (not identical with the crystal or amorphous phases!) can be mixed with a boro-silicate glass and can molten together and then subjected to a special temperature reducing process. After that product will be leached to reduce boron and to receive an open porous body. The product prepared is completely different from the instant product with respect to the crystal phases. The Examiner fails in its conclusion on page 8 line 1-6 because the product in Berger:

- is a shaped body (Formkörper) without X-ray amorphous phase (see the whole specification)
- has a special structure according to the temperature reducing process – see specification page 2 line 68 to page 3 line 2: surprisingly a spinodale demixing takes place with a mutual penetration structure
- contains no diphosphates
- contains no chain phosphates
- contains only crystals of $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$ or $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$ or $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$ which are not contained in the instant invention.

From that the skilled in the art would not combine Berger with any of the other patents cited because the prior art did not suggest the combination.

The Court of Appeals acknowledged that point of view in the decision in re Fritch (23 USPQ 2d 1780 (1783, 1784) and applied it for combination inventions: "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so ..."

Applicants further traverse the opinion of the Examiner that claims 1-13 are unpatentable over Gross et al. (US 4239113), Broemer et al. (US 3922155) and Constantz et al. (US 6002065).

Gross et al. and Broemer et al. are not relevant because they claim glass ceramics and bone cements, respectively, which comprise shares of 20-60% SiO_2 . Such ceramics or cements are not resorable but for use of long lasting artificial bones (Gross et al.: col. 6 line 9; Broemer et

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al.: abstract last 2 lines and e.g. col. 9 line 62-67).

Constantz et al teaches kit for preparing a calcium phosphate cement composition which is a calcium phosphate mineral – see claim 1 col. 11 line 11. Such a mineral is a solid and not biological resorbable because that would be in contrast to its function: "to introduce relatively long lived structures into the body to provide the necessary stability and support required for fillers, prosthetic devices and the like" (col. 10 line 63-67).

Double Patenting

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/689,219 (your ref Your Ref.: P208303US-WT/br) in view of U.S. Patent No. 4,239,113 to Gross et al. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/689,217 in view of Gross.

The position of the Examiner can be found on pages 11-12 of the Office Action.

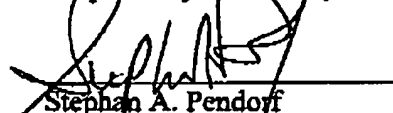
Applicants respectfully traverse in view of the amendment of claim 1 to recite specific materials and process parameters. These clearly distinguish the present invention from the invention of copending Application No. 10/689,217.

Accordingly, withdrawal of the obviousness type double patenting rejection is respectfully requested.

Entry and favorable consideration prior to consideration are respectfully requested.

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Respectfully submitted,


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